ABC TV PHILADELPHIA

What is the current regulation for the emissions of ETO with regard to sterilization facilities?

Ethylene oxide sterilization facilities are covered under the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Ethylene Oxide Commercial Sterilization and Fumigation Operations. The standards were issued in April of 2006. A review of those standards is currently underway.

Proposed Rule changes for sterilizations facilities are currently under review? what are those possible changes? and what is the process of final approval and when may that happen?

EPA is in the process of reviewing the NESHAP for Ethylene Oxide Commercial Sterilization and Fumigation Operations and we expect to issue a proposed rule in 2022. The agency is currently gathering data from companies through an Information Collection Request (ICR). These data will inform the proposal and we cannot speculate on the substance of the proposal at this time. Once issued, the public will have time to comment on the proposed rule, and we expect to issue a final rule in 2023.

Does that include fence line monitoring? Why isn't that required? Is that a possible rule change?

We cannot speculate on the substance of the proposal regarding fenceline monitoring at this time. For current fenceline monitoring at specific facilities, you will need to check with the state.

How much ethylene Oxide is allowed to be emitted from a sterilization company? are there any proposed amounts? Do you foresee those amounts changing?

The current regulation specifies the emission reductions and limits based on the piece of equipment and the amount of ethylene oxide that the facility uses per year.([HYPERLINK "https://www.govinfo.gov/content/pkg/CFR-2015-title40-vol10/pdf/CFR-2015-title40-vol10-part63-subpartO.pdf"]).

What are background ETO levels? Is that naturally occurring? What could that be from?

EPA has learned more about the health risks from breathing air that contains ethylene oxide over a lifetime, but there is a lot about ethylene oxide that we still do not know.

One of the questions we are examining is whether ethylene oxide is in the air broadly across the U.S. – and if it is, at what levels and what the potential sources might be. Just because EtO can be measured at locations where there is not a known industrial source doesn't mean that the source of this EtO is not industrial or facility based, just that we aren't certain which source it is coming from. We have a fact sheet that explains more about our work to understand background levels of EtO at: [HYPERLINK "https://www.epa.gov/system/files/documents/2021-10/background-eto-explainer-doument.pdf"]

A proposed rule was scheduled for 2021 with regard to ETO. Has that done?

EPA issued a final rule for the Miscellaneous Organic Chemical NESHAP (MON) on August 12, 2020. More information is available here: [HYPERLINK "https://www.epa.gov/stationary-sources-air-pollution/miscellaneous-organic-chemical-manufacturing-national-emission"]

In addition, in June 2021, we announced that we intend to reconsider certain aspects of the 2020 air regulation "National Emission Standards for Hazardous Air Pollutants: Miscellaneous Organic Chemical

Manufacturing (MON) Residual Risk and Technology Review" in response to five administrative petitions. The Agency will issue a Federal Register notice initiating public review and comment soon.

For workers what does the interim decision entail for protective clothing?
Workers exposed to EtO as a part of their jobs must wear specialized protective equipment where required by EPA and OSHA standards. You can learn more here: [HYPERLINK "https://www.epa.gov/ingredients-used-pesticide-products/ethylene-oxide-eto"]

Is Braun and the ETO sterilization sector covered under TRI?

By law, only certain facilities are required to report to EPA's Toxics Release Inventory: those which meet all three reporting criteria (i.e., in a covered sector; have at least ten full-time employee-equivalents; and manufacture, process, or otherwise use a listed chemical above reporting thresholds). According to the 2017 NAICS Manual, facilities that primarily engage in contract sterilization fall under NAICS code 561910 ("Product sterilization and packaging services"), which isn't covered by TRI reporting criteria. Any facility not covered by all TRI reporting criteria is not required to report.

However, B Braun in Allentown, PA classifies itself as a "Surgical and Medical Instrument Manufacturing" facility (NAICS 339112), which *is* a NAICS code regulated by TRI. The facility has reported to TRI every year since 1987, and will be required to report as long as it meets all three TRI reporting criteria.

In addition to TRI, this facility reports to several other EPA programs. To see a summary of a facility's reporting or compliance history, search for the facility in EPA's Enforcement and Compliance History Online (ECHO) tool: [HYPERLINK "http://www.echo.epa.gov"].

IF so, where do we find those reports related to a specific facility?

You can search by facility name within the [HYPERLINK "https://edap.epa.gov/public/extensions/newTRISearch/newTRISearch.html"] or TRI Search Plus tools to find Braun's TRI data. To access all of Braun's reporting forms back to 1987, use Envirofacts: [HYPERLINK "https://enviro.epa.gov/enviro/trisquery.dcn_details?tris_id=18018BRRNM824TW"]

According to the TRI map, Braun released 10000-100000 lbs in 2019. What does that mean? Put that into perspective?

EPA is unsure of what specific TRI map you are referring to and how you arrived at 10000-100000 lbs of release quantities reported by Braun for 2019. For 2019, Braun reported releasing 2,791 pounds of ethylene oxide (EtO) into the air: 240 pounds were reported as fugitive or non-point air emissions, and the remaining 2,551 pounds were reported as stack or point air emissions. Braun also reported to TRI in 2019 for ethylene glycol, but no environmental release quantities were reported by the facility.

See [HYPERLINK "https://enviro.epa.gov/enviro/tri_formr_v2.fac_list?rptyear=2019&facopt=tris_id&fvalue=18018BRRNM824TW&fac_search=fac_equal&postal_code=&city_name=&county_name=&state_code=&industry_type=&bia_code=&tribe_Name=&tribe_search=fac_beginning"] to review Braun's ethylene oxide and ethylene glycol TRI reporting form submissions for 2019.

This facility ranks 17 out of the 111 facilities that reported air releases of ethylene oxide to TRI in 2019; 16 facilities reported releasing more pounds of EtO into the air than B Braun.

[HYPERLINK "https://www.epa.gov/toxics-release-inventory-tri-program/find-understand-and-use-tri"]

How does state law differ in those states compared to PA with regard to newest and best practices of control?

For questions about Pennsylvania state laws relating to EtO we recommend that you reach out to the Pennsylvania Department of Environmental Protection.